on a product that is inevitably produced by those practicing the prior art would effectively remove that prior art from the public domain. As the court of appeals correctly held, petitioners are not entitled to such a patent.

A. In Order To Protect The Public's Right To Exploit The Public Domain, Patent Protection Applies Only To Novel Inventions

The Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. Art. I, § 8, Cl. 8. As this Court has explained, the Patent Clause "contains both a grant of power and certain limitations upon the exercise of that power." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Of particular relevance here, "when [a] patent expires the monopoly created by it expires, too, and the right to make the article * * * passes to the public." *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 230 (1964); see *Bonito Boats*, 489 U.S. at 152-153. "Congress may not * * * 'authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.'" *Id.* at 146 (quoting *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966)).

Pursuant to those directives, "§ 102 of the Patent Act * * * exclud[es] ideas that are in the public domain from patent protection." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998). In relevant part, Section 102 provides:

A person shall be entitled to a patent unless—

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in the country more than one year prior to the date of application for patent in the United States.

35 U.S.C. 102(a) and (b).

Section 102 is an integral part of the patent system's "carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff*, 525 U.S. at 63. When a patent expires, the knowledge disclosed in the patent is dedicated to the public. "Where the public has paid the congressionally mandated price for disclosure," "the subject matter of the patent passes to the free use of the public as a matter of federal law." *Bonito Boats*, 489 U.S. at 152; accord *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23, 33-34 (2003). "[F]ree exploitation" of knowledge is the rule, "to which the protection of a federal patent is the exception." *Bonito Boats*, 489 U.S. at 151.[2]

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[2] In the pharmaceutical context, Congress has particularly emphasized the importance of protecting the public domain. Before 1984, "the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term," because the manufacturer of a generic drug could not begin to seek regulatory approval to market its drug until related patents expired. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 670 (1990). Congress responded by enacting a new

B. The Prior Art Inherently Anticipated PHC Hemihydrate Regardless Of Whether A Person Skilled In The Art Would Have Recognized That Inherent Disclosure At The Time The Prior Art Was Created

1. The prior art may anticipate a claimed invention, and thereby render it non-novel, either expressly or inherently. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002), cert. denied, 538 U.S. 907 (2003). Express anticipation occurs when the prior art expressly discloses each limitation (*i.e.*, each element) of a claim. *Ibid.* In addition, "[i]t is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *Ibid.* Inherency looks to whether a matter is "necessarily" present in the prior art; it "may not be established by probabilities or possibilities." *Scaltech Inc.* v. *Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). Thus, as petitioners correctly concede (Pet. 11), "[a] claimed invention may be inherently anticipated by a prior art disclosure if the claimed invention necessarily or inevitably flows from the prior art." See, *e.g.*, *Cruciferous Sprout*, 301 F.3d at 1349; *Atlas Powder Co.* v. *Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

The court of appeals correctly applied that undisputed legal principle in holding that, on the facts as found by the courts below, the '196 patent inherently anticipated PHC hemihydrate because "the record shows

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approval process for generic drugs in the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, that permits competing drugs to be marketed as soon as related patents expire. *Eli Lilly*, 496 U.S. at 671.

that the manufacture of PHC anhydrate according to the '196 patent necessarily results in the production of PHC hemihydrate." Pet. App. 20a; see *id.* at 9a ("the anhydrate form inevitably changes into the hemihydrate form"); *id.* at 19a ("producing PHC anhydrate according to the '196 patent inevitably results in the production of at least trace amounts of anticipating PHC hemihydrate"); *id.* at 22a ("the record contains clear and convincing evidence that production of PHC anhydrate in accordance with the '196 patent inherently results in at least trace amounts of PHC hemihydrate"); *id.* at 19a ("The '196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate.").

As the court of appeals explained, the patent claim at issue here—which reads in its entirety "Crystalline paroxetine hydrochloride hemihydrate"—covers "PHC hemihydrate without limitation." Pet. App. 10a. In other words, it covers even "trace amounts" of the "bare compound." *Id.* at 23a. Because PHC anhydrate was part of the prior art and practicing that prior art inevitably produces PHC hemihydrate, the anhydrate inherently anticipated the hemihydrate.[3]

2. Petitioners nonetheless argue (Pet. 13-17) that the '196 patent did not inherently anticipate PHC hemihydrate because the hemihydrate's creation by the prior art was unintentional and unforeseen. According to petitioners (Pet. 14), "a person of ordinary skill in the art

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[3] One of petitioners' *amici* argues that the court of appeals' determination that the practice of the prior art inevitably produces the hemihydrate is not supported by the district court's findings. See PhRMA Am. Br. 6. That fact-bound contention does not warrant review, however, and moreover it does not appear to be included in the question presented. See Pet. i.

must have been able to know or appreciate th[e] inherent subject matter *before* the subsequent claim was made" in order for the doctrine of inherent anticipation to apply. Petitioners are mistaken.

In *General Electric*, this Court held invalid a patent related to a light bulb that was particularly strong because the interior surface of the glass was frosted by etchings. 326 U.S. at 246-249. The prior art included similarly frosted bulbs, but did not expressly disclose that the frosting improved the bulbs' strength. *Id.* at 247. This Court observed that although the patent applicant "found latent qualities in an old discovery and adapted it to a useful end," "[i]t is not invention to perceive that the product which others had discovered had qualities they failed to detect." *Id.* at 248-249. As the Court explained, "[i]f A without mentioning the element of strength patented a bulb which was extra strong, B could not obtain a patent on the bulb because of its strength, *though he was the first to recognize that feature*." *Id.* at 247 (emphasis added). The claimed "strengthening was inherent in the [prior art] method," and was therefore not patentable, even though the prior art had not "given any indication that [it] resulted in any strengthening of the glass." *Id.* at 246-247. Accord *Ansonia Brass*, 144 U.S. at 18 (holding that patent applicant "had no right to claim the feature of incombustibility as his invention" because a feature of an existing product or process is not patentable "even if the new result had not before been contemplated").

Following this Court's lead, the Federal Circuit has repeatedly held that "[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art" because "[a]rtisans of ordinary skill may not recognize the inherent characteristics or functioning of

the prior art." *Atlas Powder*, 190 F.3d at 1347; accord *Schering*, 339 F.3d at 1377; *Cruciferous Sprout*, 301 F.3d at 1349; *Titanium Metals Corp. of Am.* v. *Banner*, 778 F.2d 775, 780, 782 (1985). Those longstanding precedents of this Court and the Federal Circuit amply support the court of appeals' holding in this case that "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created." Pet. App. 18a.

3. Petitioners seek (Reply Br. 3-4) to distinguish the *General Electric* line of cases on the ground that they involve inherent characteristics of previously known products, as opposed to separate products. According to petitioners (*ibid.*), the hemihydrate is not a characteristic of the anhydrate, but instead is a separate product. As the Federal Circuit recognized in *Schering*, however, that is a distinction without a difference in this context, in which the manufacture of a previously known compound inevitably produces a newly identified one. 339 F.3d at 1379-1380. In that circumstance, the creation of the newly identified compound is an inherent characteristic of the prior art compound.

As the *Schering* court also recognized, a failure to apply ordinary principles of inherent anticipation in this context would enable patent applicants to withdraw prior art compounds from the public domain whenever those compounds (or their production or use) inevitably produce a newly discovered compound. 339 F.3d at 1379. The law simply does not permit that result. It is a bedrock principle of patent law that "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it

also covers subject matter not in the prior art." *Atlas Powder*, 190 F.3d at 1346; see *Schering*, 339 F.3d at 1379; pp. 7-8, *supra*.

That concern is especially pronounced here, because this case involves "an express attempt [by petitioners] to prevent [respondents] from practicing the '196 patent upon its expiration." Pet. App. 22a. Petitioners' theory is that respondents necessarily infringe the '723 patent because they cannot manufacture the prior art anhydrate covered by the '196 patent without creating undetectable but trace amounts of the hemihydrate at the same time. *Id.* at 14a.[1] Any such attempt to prevent a party from practicing the prior art is barred by the fundamental patent-law principle that "[t]hat which infringes if later, anticipates if earlier." *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 203 (1894) (citations omitted); see *Schering*, 339 F.3d at 1379; Pet. App. 14a. As the court of appeals correctly explained, "if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the '723 patent." *Id.* at 14a.

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[1] Although petitioners argue (Reply Br. 8) that respondents could avoid infringement by producing PHC anhydrate in a laboratory that had not been seeded with PHC hemihydrate, the court of appeals concluded that "PHC anhydrate made in accordance with the '196 patent converts into PHC hemihydrate both with and without seeding." Pet. App. 10a; see *id.* at 20a-21a. In any event, the prior art was not limited to production of PHC anhydrate solely in a laboratory carefully screened to be free of hemihydrate "seeding," so petitioner's theory would necessarily (and impermissibly) withdraw prior art activities from the public domain. As the court of appeals correctly explained, the "law does not require [respondents] to take extraordinary measures to practice the prior art without infringing claim 1 of the '723 patent." *Id.* at 22a (citing *Atlas Powder*, 190 F.3d at 1349-1350).

Petitioners attempt to avoid that conclusion by arguing that practicing the prior art (*i.e.*, manufacturing the anhydrate covered by the '196 patent) would *not* have infringed the '723 patent before petitioners' discovery of the hemihydrate, because it was only the "seeding" effect resulting from that discovery that caused the prior art to begin producing PHC anhydrate containing trace amounts of PHC hemihydrate. Pet. App. 15a. But that argument is simply inconsistent with the facts found by the courts below. The district court found that the hemihydrate was produced in detectable quantities by the operation of petitioners' *anhydrate* manufacturing process in December 1984. *Id.* at 125a. Thus, contrary to petitioners' suggestion, the manufacture of the anhydrate itself—*i.e.*, the practice of the prior art—led to the creation of the hemihydrate. The court of appeals thus concluded that "[t]he '196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate." *Id.* at 19a. The doctrine of inherent anticipation prevents petitioners from blocking the practice of the prior art covered by the expired '196 patent.

4. Although petitioners argue (Pet. 22) that the court of appeals' decision "threaten[s] the innovation that the patent laws are designed to protect," the decision below preserves ample incentives for innovation. As the court of appeals explained, its holding "merely precludes patent protection for the bare compound PHC hemihydrate," leaving narrower patent protection available "through proper claiming." Pet. App. 23a.

The patent at issue here claims not only the bare compound PHC hemihydrate (claim 1), but also PHC hemihydrate in "substantially pure form" (claim 2), as well as an "anti-depressant pharmaceutical composition

comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier" (claim 5). Pet. App. 192a. The latter claims do not raise the concerns presented here, because their claimed subject matter is not inevitably created by the practice of the '196 patent. Providing patent protection for such claims would therefore reward innovation without preventing the public from practicing the prior art covered by the expired '196 patent.

Petitioners therefore err in asserting (Pet. 23) that the decision below will "substantially decrease[ ]" incentives to research new pharmaceutical compounds. Like petitioners in this case, researchers who discover novel drug compounds routinely include claims of varying scope and breadth in their patent applications rather than claiming only the "bare compound" in all-encompassing terms. In that fashion, they may retain protection for the actual, practical applications of their new discoveries even if their broader claims to the bare compound are ultimately rejected. The ability to obtain such patent protection provides ample incentives for innovation. What patent applicants cannot do is to receive patent protection for trace amounts of a substance that was inevitably produced by the practice of the prior art, and thereby withdraw that prior art from the public domain and make the exploitation of expired patents difficult or impossible.

C. The Court of Appeals' Decision Does Not Conflict With Decisions Of This Court Or Create Confusion In The Federal Circuit's Jurisprudence

1. Contrary to petitioners' contention, the court of appeals' decision does not conflict with decisions of this

Court involving unwitting or accidental discoveries. See Pet. 2-5, 11-13 (citing *Tilghman* v. *Proctor*, 102 U.S. 707 (1881); *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902); *Eibel Process Co.* v. *Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923)). The cases cited by petitioners are distinguishable for at least three reasons: they did not involve attempts to patent pre-existing products; they did not involve patents that would prevent the public from practicing the prior art; and it was not clear in those cases that the prior art had in fact inevitably produced the allegedly inherent result.

The court of appeals stressed that its holding "merely preclude[d] patent protection for [a] bare compound" that was inevitably created by the practice of the prior art. Pet. App. 23a. In contrast, neither *Tilghman* nor *Carnegie Steel* involved a patent on a product. The patents at issue in those cases were instead process patents, covering processes for purifying fats and oils, and for making steel, respectively. *Tilghman*, 102 U.S. at 708; *Carnegie Steel*, 185 U.S. at 430. That distinction is critical, because a process patent (unlike a patent on a particular composition of matter) is not anticipated merely by a showing that the ultimate output of the process was already known in the prior art. In *Carnegie Steel*, this Court expressly distinguished process from product patents by explaining that although "[a] mechanical patent is anticipated by a prior device of like construction and capable of performing the same function," "it is otherwise for process patents," which "can only be anticipated by a similar *process*." *Id.* at 424 (emphasis added). Thus, a patent on a new process does not prevent others from using prior art processes, whereas under petitioners' theory their patent on a "new" product would block others from manufacturing

the prior art product that inevitably produces the new one.

The *Eibel* patent, which involved substantially increasing the pitch of a wire cloth sieve used in papermaking machines in order to increase the rate of production, 261 U.S. at 46-47, is distinguishable on similar grounds. The inventor in *Eibel* did not seek a patent covering the pre-existing machine, but instead sought to patent an improved machine not disclosed by the prior art. *Id.* at 58-60. A prior art machine does not anticipate a newer and better machine, and a patent on the new machine does not preclude the practice of the prior art.

As the Federal Circuit recognized in *Schering*, 339 F.3d at 1378, it was also unclear in the cases relied on by petitioners whether the practice of the prior art had actually produced the allegedly inherent result. See *Tilghman*, 102 U.S. at 711-712 ("*If* the acids were accidentally and unwittingly produced * * * it would be absurd to say that this was an anticipation of Tilghman's discovery.") (emphasis added); *Eibel*, 261 U.S. at 66 ("[W]e find no evidence that any pitch of the wire, used before Eibel, had brought about such a result."); *Carnegie Steel*, 185 U.S. at 424 ("[N]one of [the prior art devices] in practical operation seems to have been effective to secure the desired result."). In contrast, the court of appeals stressed that "the manufacture of PHC anhydrate according to the '196 patent necessarily results in the production of PHC hemihydrate." Pet. App. 20a; see p. 10, *supra*.[5]

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[5] Petitioners' reliance (Pet. 18) on *Ritter* v. *Rohm & Haas Co.*, 271 F. Supp. 313, 346 (S.D.N.Y. 1967), is misplaced, because the district court there upheld a patent on a "new process, wholly unknown

2. Nor is there any confusion in the Federal Circuit's jurisprudence regarding inherent anticipation. Consistent with this Court's *General Electric* and *Ausonia Brass* decisions, the Federal Circuit has long held that characteristics of known products are inherently anticipated even if they were not previously recognized by persons skilled in the art. See, *e.g.*, *Atlas Powder*, 190 F.3d at 1347; *Cruciferous Sprout*, 301 F.3d at 1350; *Titanium Metals*, 778 F.2d at 782. And the Federal Circuit made clear in *Schering*, and reaffirmed in this case, that it "sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter," such as a compound that was inevitably created by practicing the prior art. *Schering*, 339 F.3d at 1379; see Pet. App. 18a.

In so holding, the Federal Circuit expressly distinguished the earlier decisions on which petitioners principally rely (Pet. 14, 19-20). *Schering* explained that *Continental Can Co. USA* v. *Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), "does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date." 339 F.3d at 1377. Instead, the question in *Continental Can* was whether a prior art plastic bottle had in fact possessed a particular feature (hollow as opposed to solid ribs), and the court remanded for a factual determination of "whether [the prior art] necessarily produced 'hollow' ribs." *Continental Can*, 948 F.2d at 1269; see *Schering*, 339 F.3d at 1377-1378. In contrast, the court of appeals here held

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to" the prior art, as opposed to a product inevitably created by the prior art.

that the practice of the '196 patent inevitably produces PHC hemihydrate. Pet. App. 19a-20a.

Although *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964), contains some reasoning supportive of petitioners' position, the actual holding of the case was only that a substance was not anticipated by a prior art process when "[t]here [was] no positive evidence that [the substance] was produced inherently." *Id.* at 999. As the decision below explains, *Seaborg*'s holding is therefore consistent with the judgment in this case, because the record here reveals that the '196 patent does in fact "result[] in the production of the claimed PHC hemihydrate." Pet. App. 23a. To the extent, if any, that *Seaborg*'s reasoning is in tension with earlier and later holdings of the court of appeals and with this Court's decisions in *General Electric* and *Ausonia Brass*, it does not state the law, and provides no basis for review.[6]

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[6] Petitioners also rely (Pet. 18-19) on district court decisions for the proposition that the unrecognized production of a substance does not preclude a patent on that substance. Any perceived conflict between those cases and the decisions of the Federal Circuit, of course, would not merit review. Cf. Sup. Ct. R. 10(a). Moreover, those cases are inapposite. They involved the question whether a patent applicant had committed fraud on the patent office by not disclosing that tetracycline had been previously produced in trace amounts pursuant to a prior art method of producing a different substance. *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 498 F. Supp. 28, 35-36 (E.D. Pa. 1980), aff'd, 676 F.2d 51 (3d Cir. 1982); *North Carolina* v. *Charles Pfizer & Co.*, 384 F. Supp. 265, 277-278 (E.D. N. Car. 1974), aff'd, 537 F.2d 67 (4th Cir.), cert. denied, 429 U.S. 870 (1976). Although some courts found that there was no fraud on the patent office, the Federal Trade Commission concluded otherwise, and the Sixth Circuit affirmed that determination. *Charles Pfizer & Co. v. FTC*, 401 F.2d 574, 578 (1968), cert. denied, 394 U.S. 920 (1969). In any event, none of those cases involved an attempt to prevent the public from practicing the

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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prior art, and the Federal Circuit's subsequent decisions in *Schering* and this case have clarified that an applicant cannot obtain a patent on a bare compound that was inevitably produced by the prior art.

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IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,

Petitioners,

v.

APOTEX CORPORATION, APOTEX, INC. AND TORPHARM, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner

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November 16, 2005

QUESTION PRESENTED

Amicus asks the Court to grant review on the question presented in the petition, which amicus casts as follows:

Under 35 U.S.C. § 102(b) a person is not entitled to a patent if it is anticipated. That is, a person is not entitled to a patent if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." This Court has established that accidental results, not intended and not appreciated, do not constitute anticipation. *Tilghman v. Proctor*, 102 U.S. 707 (1881); *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923).

The question presented is whether the United States Court of Appeals for the Federal Circuit erred by departing from this standard to find that anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the art is created and relied on this erroneous standard to sever the issue of anticipation from the facts as found by the trial court and to find the patent in this case invalid as anticipated.

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INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents more than thirty of the country's leading research-based pharmaceutical and biotechnology companies.[1] In 2004, PhRMA's members invested an estimated $38.8 billion in the research and development of new medicines. PhRMA's members recognize the importance of innovation to fighting crippling and deadly diseases and are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Given the unavoidable costs of cutting-edge pharmaceutical research and development, PhRMA's members rely upon the availability of patents on their discoveries to recoup the costs of their investments. The Federal Circuit's decision in this case conflicts with the protection for patented inventions set forth in section 102 of the Patent Code, 35 U.S.C. § 102, and undermines the certainty of an entire class of patents, patents on previously unrecognized compounds, vital to the development of new and beneficial pharmaceuticals.

STATEMENT

> The patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing

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[1] GlaxoSmithKline, petitioners' corporate affiliate, is a member of PhRMA but has not participated in the decision to file or the preparation of this brief. In addition, undersigned counsel for PhRMA was counsel for petitioner SmithKlineBeecham Corporation in the trial and appellate proceedings ultimately resolved in *Apotex v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), an unsuccessful challenge by respondent Apotex, Inc. to the United States Food and Drug Administration's listing of certain other patents, not involved in the instant matter, in connection with the Paxil® drug product.

patents, as well as negation of searches for the beneficial components of existing materials.

App. 5[illegible] (Newman, J., dissenting from denial of rehearing en banc).

Judge Newman's dissent from denial of rehearing below correctly notes the serious implications that flow from the Federal Circuit's decision in the instant case. The Federal Circuit, reversing the district court, held invalid a patent claiming a drug substance (crystalline paroxetine hydrochloride hemihydrate or "PHC hemihydrate") as lacking novelty over a prior art reference (U.S. Patent No. 4,007,196 or "the '196 patent"), even though: (1) the prior art did not "describe" the claimed compound, (2) there was no evidence that anyone in the prior art had ever produced the compound, and (3) no one had ever recognized or identified the compound before the named inventors.

Nevertheless, the Federal Circuit held that the '196 patent "inherently anticipates" the patent claim, finding the practice of the '196 patent "naturally results" in the later claimed chemical compound in unknown and unknowable amounts. App. 19a. In so holding, the Federal Circuit simply discarded the detailed factual findings made by the district court following a three-week bench trial, and, without finding those facts clearly erroneous, announced a new standard for "inherent anticipation" so vague and indeterminate as to allow a patent to be held invalid without any meaningful evidence that the claimed subject matter ever previously existed.

Recognition of that which has previously been overlooked is fundamental to invention. For example, the broad spectrum antibiotic tetracycline was discovered from

study of the existing Aureomycin antibiotic,[2] and discovery of a new crystalline form for ranitidine hydrochloride, more suitable for commercialization, lead to the anti-ulcer medication Zantac®.[3]

Because invention does not necessarily spring, like Athena, fully formed from the mind of its creator, but rather often develops gradually, through manipulation of known elements, the danger is great that a genuine and valuable advance will erroneously appear, through hindsight, to lack novelty. The law recognizes, and protects against, this danger through the imposition of strict standards on those who would attack a patent as invalid: the challenger must prove, with clear and convincing evidence, that the patent claim lacks novelty – that the claimed subject matter was previously, as a matter of clear fact, either "patented or described in a printed publication . . . or in public use or on sale . . . ." 35 U.S.C. § 102(b).

The Federal Circuit's departure from these requirements, and its creation of a new test for "inherent anticipation" that allows invalidation of a patent detached from any meaningful fact finding, has far reaching implications. Accordingly, PhRMA submits that review by this Court is warranted.

FACTUAL BACKGROUND

This case arose in 1998 when SmithKline sued Apotex under 35 U.S.C. § 271(e)(2) for infringing United States Patent No. 4,721,723 ("the '723 patent") by seeking FDA approval to sell a generic, paroxetine-based antidepressant.

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[2] *See Chas. Pfizer & Co. v. Barry-Martin Pharms., Inc.*, 241 F. Supp. 191 (S.D. Fla. 1965).

[3] *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1045-46 (Fed. Cir. 1995).

After an approximately three-week trial in January, 2003, the district court (Circuit Judge Richard R. Posner, sitting by designation) held that claim 1 of the '723 patent was not infringed and was not invalid under 35 U.S.C. §102. App. 181a-82a. Apotex had argued that the '196 patent "literally" anticipated claim 1 of the '723 patent – that is, that the prior disclosure of paroxetine compounds rendered invalid a patent on the later-discovered PHC hemihydrate. Judge Posner rejected this argument, labeling it "frivolous." *Id.* at 131a. Judge Posner wrote that there "is no mention of hemihydrate in the patent . . . and the hemihydrate polymorph of paroxetine was unknown either when the ['196] patent application was filed or in 1977 when the patent was granted." *Id.* Judge Posner also rejected Apotex's argument that claim 1 of the '723 patent was inherently anticipated by the '196 patent, finding that Apotex failed to establish inherency by the "clear and convincing evidence . . . required to invalidate a patent." *Id* at 132a.

SmithKline appealed the finding of non-infringement. Apotex cross-appealed on a finding the claims were not invalid based on a prior public-use, and its briefs on appeal did not argue for reversal of the trial court's findings rejecting inherent anticipation. On April 23, 2004, a Federal Circuit panel reversed the district court's claim construction. The panel, however, found the claims of the patent invalid under § 102(b) for public use. App 60a.

SmithKline petitioned the Federal Circuit to review the public use finding en banc. On April 8, 2005, the Federal Circuit granted SmithKline's petition, vacated "the panel's original opinion addressing the issue of experimental use" and remanded the case to the original panel. App. 57a. On the same day, the original panel issued a revised opinion, this time finding claim 1 of the '723 patent invalid as inherently anticipated by the '196 patent. App. 1a.

The panel, in its revised opinion, left the district court's findings of fact largely intact. App. 9a. Thus, it left undisturbed the lower court's findings that PHC hemihydrate had first been detected in 1985 and that no one could say when that compound had first come into existence. The panel's anticipation holding was instead based on an inference from the court's belief that PHC hemihydrate had been "unwittingly" made by SmithKline while attempting to practice the '196 patent and that "neither Apotex nor SmithKline can *presently* produce PHC anhydrate that does not contain at least trace amounts of PHC hemihydrate." *Id.* at 9a-10a (emphasis added).

Judge Newman dissented from the court's en banc order. She observed that the "findings of chemical fact by this court are devoid of scientific support" and correctly noted that:

> The district court's finding that it had not been established that the hemihydrate was produced in 1975 is in accord with the evidence, and surely has not been shown to be clearly erroneous. There is no evidence to support the panel's current finding that the '196 patent "discloses in an enabling manner the production of the PHC hemihydrate." The evidence before the district court did not show that disclosure and enablement, and did not show that the hemihydrate was produced in 1975, even inherently and undetected.

App. 57a-58a.

REASONS FOR GRANTING THE WRIT

A. The Federal Circuit's Fact-Finding Departs From the Federal Rules of Civil Procedure and Prior Opinions of This Court.

In holding the hemihydrate anticipated, the Federal Circuit made a finding of fact. Whether a patent is anticipated is a question of fact. *See Glaxo*, 52 F.3d at 1047.

And the facts that must be found are set forth in the Patent Code: "A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." 35 U.S.C. § 102(b). What is more, to invalidate a patent, these facts must be shown with clear and convincing evidence. 35 U.S.C. § 282.

The Federal Circuit's decision in this case depends upon its finding, as a matter of clear fact, that "the '196 patent discloses a method of manufacturing [paroxetine] that naturally results in the production of PHC hemihydrate." App. 19a. The district court neither made that finding nor can that finding be inferred from the findings the district court did make. The district court found not only that it was a "reasonable inference" and "in all likelihood" that PHC hemihydrate did not exist until December 1984 but also that Apotex failed to prove by clear and convincing evidence that PHC hemihydrate "was inherent" in the prior art paroxetine products. App. 126a, 132a, 146a. The district court found that Apotex only demonstrated the appearance of PHC hemihydrate years after the discovery of earlier paroxetine compounds and that when considered in light of "uncertainties in the scientific community concerning provenance and causality of polymorphs," that bare correlation failed to prove inherency. *Id.* at 132a. The Federal Circuit provided no analysis as to why that finding constituted clear error by the district court.

This petition thus presents the important question of whether the court of appeals may reverse the district court and enter a judgment of patent invalidity for anticipation, a determination of fact, without following the requisite